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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,519	06/06/2001	Timothy C. Farries	4-30443B/D1	6920

1095 7590 07/17/2003

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT PAPER NUMBER

1644

DATE MAILED: 07/17/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/875,519

Applicant(s)

FARRIES ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

This application is a divisional of U.S. Application Serial Number 09/142,334 which is a 371 continuation of PCT/GB97/00603.

Claims 2-36 and 38-50 have been canceled previously.

Claims 1, 37 and 51-56 have been canceled herewith.

Claim 57 has been added, is currently pending and are the subject of examination in the present Office Action.

Claim Rejections - 35 USC § 112

1. Claim 57 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA sequence encoding a modified human C3 protein of SEQ ID NO 22 with one or more of the following mutations: E992S, D993A, D996S, A997Q, E998S, R999G, L1000M, K1001N, H1002I, V1005H, Q1152R, E1153K, K1155F, R954E, the double mutant R954Q + E955G, and REA1591-3stop, does not reasonably provide enablement for a DNA sequence encoding any modified human C3 protein comprising all frame shift mutations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

Claim 57 is a rewritten version of previous claim 55 and is drawn to a DNA sequence encoding a modified human C3 protein which is capable of forming a stable C3 convertase comprising one or more of the mutations E992S, D993A, D996S, A997Q, E998S, R999G, L1000M, K1001N, H1002I, V1005H, Q1152R, E1153K, K1155F, R954E, the double mutant R954Q + E955G, REA1591-3stop or frame shift. However, while the specification may be enabling for a particular frame shift mutation, the claim as drafted reads on any frame shift mutation within the sequence of the modified C3 protein. The specification does enable the full scope of frame shift mutations within C3, as only a limited number of examples are disclosed and the artisan is not provided sufficient guidance by the specification in regards to the structure and/or functional characteristics of other frame shift mutations which may occur or be engineered into the C3 molecule. Further, the only sequence for which the specification teaches that the unmodified residues (e.g., 'E' of E992S) are located at the recited positions (e.g., '992' of E992S) for the

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aforementioned modifications(e.g., 'S' of E992S) is SEQ ID NO: 22. It would require an undue amount of experimentation on the part of the artisan to determine whether such modifications could be made any C3 protein, including human proteins which an artisan might generically term "C3," or would be effectively equivalent to modifications of SEQ ID NO: 22 without specific guidance from the specification. Redrafting the claim to recite SEQ ID NO: 22 and specific frame shift mutations can overcome this ground of rejection.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue experimentation to practice the claimed invention.

3. Claim 57 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 is ambiguous in the recitation of "a modified human C3 protein." The claim is drawn to specific modifications of a specific protein sequence, however the claim does not positively identify the sequence. It is suggested that Applicant amend the claim to recite that the human C3 protein being modified is that disclosed in the specification as SEQ ID NO: 22.

Conclusion

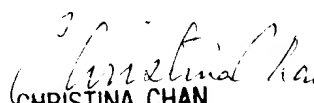
4. No claim is allowed.

5. In view of the new ground of rejection, this Office Action is made **NON-FINAL**.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
July 15, 2003


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600